**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| **In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION** | **MDL No. 1456**<br>**Master File No. 01-12257-PBS**<br>**Subcategory Case No. 06-11337** |
| **THIS DOCUMENT RELATES TO:**<br><br>*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*,<br>Civil Action No. 03-11226-PBS | **Hon. Patti B. Saris** |

**DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICAL INC.'S BRIEF IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT**

## PRELIMINARY STATEMENT

Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") request that the Court grant summary judgment on all of California's claims against Mylan that accrued before August of 1999. The evidence in the record clearly demonstrates that California was on notice that published AWPs significantly exceeded acquisition costs by no later than July of 1998. The California False Claims Act, Cal. Gov. Code § 12650, *et seq.* (the "CFCA"), bars California from recovering claims of which it had notice more than three years prior to the commencement of an action. Since Mylan was not named as a defendant in this action until August of 2002, any CFCA claims California may have against Mylan that accrued before August of 1999 are barred.

Mylan also requests that the Court grant summary judgment in its favor on California's claims for lorazepam and clorazepate, on the grounds that they are barred by the doctrine of *res judicata* and by a release given to Mylan by the state of California. In addition,

Mylan Inc. is entitled to summary judgment on all of California's claims against Mylan Inc., as Mylan Inc. is a holding company that does not report prices for drugs.[1]

## ARGUMENT

### I. CALIFORNIA'S CFCA CLAIMS AGAINST MYLAN PRIOR TO AUGUST 1999 ARE BARRED BY THE STATUTE OF LIMITATIONS

The evidentiary record demonstrates that, by July of 1998, California was on notice of the CFCA claims it attempts to allege against Mylan in its First Amended Complaint. Since Mylan was not named in this action until the first amended *qui tam* complaint was filed in August of 2002, any claims against Mylan that accrued more than three years prior to that date are barred.

Section 12654(a) of the California Government Code limits the period in which an action under the CFCA may be filed to three years from the date of discovery:

> A civil action under Section 12652 may not be filed more than three years after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances or, in any event, no more than 10 years after the date on which the violation of Section 12651 is committed.

As used in the statute, the "date of discovery" means the date when the responsible official "either knows of the false claim or knows of facts which would lead a reasonably prudent person to suspect it." *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940, 953, 112 Cal. Rptr. 2d 329, 339 (Cal. Ct. App. 2001). *See also Beal v. Reynolds*, No. RG03 79214, 2004 WL 5064143 (Cal. Super. Ct. Jan. 5, 2004) (holding that, consistent with numerous other California cases, discovery rule "include[s] a 'should have discovered' standard") (citing *Debro*, *supra*).

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[1] Mylan also respectfully requests that this Court grant partial summary judgment on the grounds set forth in Defendants' Joint Brief In Support of Partial Summary Judgment (the "Joint Brief"). Indeed, the payments Medi-Cal made for Mylan's drugs during the relevant time period demonstrate that California has not suffered any injury for reimbursements it made for Mylan's drugs.

In *Debro*, the plaintiff alleged that monies received by the Los Angeles Raiders from the City of Oakland pursuant to a purported loan, were in fact a payoff or gift in violation of the CFCA. 92 Cal. App. 4th 940, 948, 112 Cal. Rptr. 2d 329, 334. The court held that the responsible government officials were put on constructive notice of the alleged violation at the time they signed the agreement. *Id.* at 953-54, 112 Cal. Rptr. 2d at 339. Rejecting the plaintiff's argument that it was difficult to unearth the violation because the document was called a loan agreement, the court stated that "[i]t is not necessary that all of the facts be discovered for the limitations period to commence," merely that they would have "put responsible government officials on notice to inquire about a possible false claim." *Id.* at 954-55, 112 Cal. Rptr. 2d at 340. In the drug pricing context, "[u]nder the discovery rule, the question is when there was sufficient information such that a reasonable [third party payor] in the plaintiffs' position would have been on notice to investigate the possibility that AWP had become unhinged from acquisition costs causing plaintiffs to overpay for drugs." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 78 (D. Mass. 2007).

Here, evidence in the record demonstrates that California was aware as early as 1986 that published AWPs substantially exceeded providers' costs to acquire drugs. However, two significant events establish as a matter of law that California was on notice of "the possibility that AWP had become unhinged from acquisition costs" by no later than of July of 1998:

***First***, in May of 1996, HHS-OIG published the results of its 1994/1995 survey of pharmacy acquisition costs for Medi-Cal providers in a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062). (Defendants' Joint Statement of

Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment ("Joint SOF") ¶¶ 29-32.) This report, which Medi-Cal officials assisted HHS-OIG in preparing, was part of an effort by HHS-OIG to determine an estimate of the difference between AWPs and providers' actual acquisition costs on a nation-wide level. (*Id.*) As part of its survey, HHS-OIG examined more than 2600 pharmacy invoices gather from 34 pharmacies across the state. (Joint-SOF ¶¶32.) The report found that, on average, pharmacists' invoice prices for brand-name or single source drugs were 17.5 percent below published AWPs and that invoice prices for generic or multi-source drugs were 41.5 percent below AWP. (*Id.*) John Rodriguez, the Deputy Director for Medical Care Services at the California Department of Health Services ("DHS"), the California agency that administers the Medi-Cal program, confirmed receipt of the report, indicating his hope that the report would "substantiate DHS' position that current drug ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies." (*Id.*)

***Second***, in July of 1998, the relator, Ven-A-Care of the Florida Keys, Inc. ("Relator") filed the original *qui tam* complaint in this action. (Joint-SOF ¶ 60-62.) Relator served the California Attorney General's office with a copy of the complaint and a written disclosure of substantially all the material evidence and information in its possession, as required by California Government Code Section 12652(c)(3). Although Mylan was not named, the complaint named 23 other drug manufacturers and laid out essentially the same allegations of a purportedly fraudulent scheme that is alleged against Mylan in the first amended *qui tam* complaint. (Joint-SOF ¶ 60-63.) Moreover, the complaint listed catalog and contract prices that were available to Relator for the 23 named defendants' drugs. (*Id.*)

Either of these two events, alone, would have been enough to put California on notice of the possibility that Mylan's AWPs exceeded acquisition costs. Taken together, they were more than sufficient to put California "on notice to investigate the possibility that AWP had become unhinged from acquisition costs" *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d at 78. Accordingly, at a minimum, California was on notice by no later than July 1998 of any potential claims it had against Mylan.

Since California was on notice of the alleged conduct by Mylan in July of 1998, California had "discovered" all of its potential claims against Mylan that accrued prior to then in July of 1998 as well. However, Mylan was not named in the original complaint and was not added as a defendant until Ven-A-Care amended its *qui tam* complaint in August 2002. (JOINT-SOF ¶ 62-63). Accordingly, the statute of limitations bars all of California's CFCA claims against Mylan that accrued prior to July 1999.

## II. CALIFORNIA DID NOT "OVERPAY" FOR MYLAN'S PRODUCTS

As set forth more fully in the Joint Brief, for claims paid from January 1997 to the present, California is not entitled to damages under the CFCA as a matter of law. (*See* Joint Brief at Pt. II.) The payments it made on those claims were amounts that it determined were consistent with efficiency, economy, and access to quality care, as required by Ninth Circuit precedent. Accordingly, the published prices for Defendants' products, including Mylan's products, did not cause California any injury.

Indeed, the findings in the Myers and Stauffer reports confirm that Medi-Cal's total reimbursement payments were not "overpayments" and resulted only in modest dollar payments above the provider's total cost, even when there was a so-called "mega-spread" between the published price and the provider's actual cost for a particular drug. (*See id.*)

Comparisons of the actual acquisition costs compiled by Myers and Stauffer for Mylan drugs at issue in this action to Medi-Cal reimbursement claims confirm that the same is true for Mylan's drugs. The chart below contains the following information for seven of the top Mylan drugs at issue in this case based on total Medi-Cal reimbursement payments: (a) the so-called "spread" between the published AWP and the average actual acquisition cost, as determined by Myers and Stauffer; (b) Medi-Cal's total payment for a particular reimbursement claim in 2000, based on either AWP minus five percent or FUL, plus the $4.05 dispensing fee in effect at the time; (c) the provider's total cost, which consists of the average actual ingredient cost for the drug, as calculated by Myers and Stauffer, plus $7.21, the average cost of dispensing as determined by Myers and Stauffer; and (d) the dollar margin (or loss) to the provider, which is Medi-Cal's payment minus the provider's cost.

| **Drug** | **"Spread" Between Published AWP and Provider's Cost** | **Medi-Cal Payment** | **Provider's Cost** | **Dollar Margin or Loss** |
|---|---|---|---|---|
| **Mylan's cimetidine 400 mg tablet 00378037205 (subject to an FUL)** | 3054% | $9.11 | $8.74 | $0.37 |
| **Mylan's naproxen 500 mg tablet 00378045105 (subject to an FUL)** | 1626% | $14.74 | $11.36 | $3.38 |
| **Mylan's furosemide 40mg tablet 00378021610 (subject to an FUL)** | 904% | $6.34 | $8.80 | ($2.46) |
| **Mylan's diphenoxylate/atropine tablet 00378041510** | 419% | $17.48 | $9.99 | $7.49 |
| **Mylan's spirinolactone 25 mg tablet 00378214601 (subject to an FUL)** | 326% | $13.85 | $10.13 | $3.72 |
| **Mylan's diltiazem ER 240 mg capsule 00378534001** | 176% | $36.46 | $19.65 | $16.81 |
| **Mylan's phenytoin sodium ER 100 mg capsule 00378156010** | 61.9% | $17.77 | $16.29 | $1.48 |

(*See* Declaration of Peter Brase Concerning the State of California's Claims Data ("Brase Decl.) ¶¶ 9,10,11,17.)

As these figures demonstrate, the so-called "mega-spreads" between the published prices and actual costs for the generic drugs at issue in this action do not cause "inflated" or "excessive" reimbursement payments to Medi-Cal providers who dispensed these drugs. Quite the opposite; Medi-Cal providers received mostly modest dollar margins compared to their costs, largely due to the application of FULs and Medi-Cal's inadequate (below cost) $4.05 dispensing fee. Indeed, despite large "spreads," Myers and Stauffer's findings show that Medi-Cal providers sometimes lost money dispensing Mylan drugs to beneficiaries, particularly when dispensing drugs with FULs. And even when providers did receive large dollar margins on reimbursement payments, those payments cannot be said to be "excessive." Given that providers sometimes realize only *de minimis* profits or even losses on some of the other Mylan drugs, providers likely depend on the comparatively few larger margins to make up for shortfalls on other drugs.

These generally modest dollar margins are consistent with California's obligation under federal law to make payments that balance efficiency, economy, and access to quality care. Indeed, the reimbursement rate of AWP minus 17 percent plus $7.25 that California adopted in September 2004, two years after the Myers and Stauffer reports were released, continued to result in dollar margins at these levels. For instance, in November of 2004, Medi-Cal reimbursed a provider who had dispensed 30 units of Mylan's diltiazem ER 240 mg capsule at $35.79. (Brase Decl. at. ¶18) Assuming that the provider's cost to dispense that prescription was still $19.65, the same as it was in 2000, the margin the provider would have realized from its Medi-Cal reimbursement would have been $16.14, almost exactly the same as the $16.81 profit margin the provider would have realized in 2000. (*Id.*)

In other words, after conducting the study that it was required to conduct by the Ninth Circuit to ensure that its payments were consistent with efficiency, economy, and access to quality care, California intentionally chose to continue to pay margins for Mylan's drugs that were consistent with margins it was paying before the publication of the 2002 Myers and Stauffer report. The only reasonable conclusion that can be drawn from this evidence is that the payments Medi-Cal made for Mylan's drugs both before and after September 2004 were consistent with the goals of efficiency, economy, and access to quality care. Thus, California did not suffer any injury resulting from reimbursement payments for Mylan's drugs.

## III. OTHER GROUNDS

Mylan also moves for summary judgment on the grounds listed below. *Contra Mass. v. Mylan Labs.*, No. 03-11865-PBS, 2009 U.S. Dist. LEXIS 20332, (D. Mass. March 11, 2009):

- California's claims for lorazepam and clorazepate are barred by the doctrine of *res judicata*. In December of 1998, several states, including California, brought an action against Mylan contending that Mylan improperly raised the prices for its lorazepam and clorazepate products, causing the state Medicaid programs, including California's, to overpay for those products (the "Lorazepam/Clorazepate Action"). (Statement of Undisputed Material Facts in Support of Mylan's Motion for Partial Summary Judgment ("Mylan-SOF") ¶¶ 1-15) On February 1, 2002, the District Court for the District of Columbia entered an Order and Final Judgment dismissing the Lorazepam/Clorazepate Action with prejudice. (Mylan-SOF ¶¶ 16-33). Since that action involved the same parties as this action (Mylan and California) and the same series of transactions that are at issue in this action (allegedly inflated Medicaid reimbursement payments for lorazepam and clorazepate), the doctrine of *res judicata* bars California's claims for lorazepam and clorazepate. *See Reppert v. Marvin Lumber and Cedar Co., Inc.*, 359 F.3d 53, 56 (1st Cir. 2004); *Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 713 (9th Cir. 2001).

- On January 1, 2001, the parties in the Lorazepam/Clorazepate Action, including California, entered into a settlement agreement, which called for a payment by Mylan of $100 million in exchange for a release of all claims that "could have been asserted in that action" that arose out of the "facts, matters, transactions, events, occurrences, acts, disclosures, statements, omissions, or failures to act" alleged in the Lorazepam/Clorazepate Action. (Mylan-SOF ¶¶ 16-33) Since the

claims in this action are based on the same alleged inflated prices for lorazepam and clorazepate that were at issue in the Lorazepam/Clorazepate Action, the release bars California's claims arising from alleged "overpayments" for those drugs in this action. *See Nottingham Partners v. Trans-Lux Corp.*, 925 F.2d 29, 32 (1st Cir. 1991); *Marder v. Lopez*, 450 F.3d 445, 449 (9th Cir. 2006).

- There is no basis for holding Mylan Inc. liable for the conduct alleged in the complaint. Mylan Inc. is a holding company that does not report prices for any drugs. (Mylan-SOF ¶¶ 35-38 ) Since the crux of California's complaint is that defendants' sales, marketing, and price reporting practices violated the CFCA, there is no basis to hold Mylan Inc. liable for claims in this action.

## CONCLUSION

For the reasons set forth above, Mylan respectfully requests that the Court grant this motion and enter judgment in favor of Mylan on California's claims that accrued before August of 1999, enter judgment in favor of Mylan on all of California's claims arising from reimbursement payments for Mylan's lorazepam and clorazepate products, and enter judgment in favor of Mylan Inc.

Dated: November 25, 2009

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on November 25, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Christopher C. Palermo
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